MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
RADIATION CONTROL PROGRAM

REGULATORY GUIDE NO. 5.0
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GUIDE FOR THE PREPARATION OF APPLICATIONS FOR LICENSES FOR MEDICAL USE OF RADIOACTIVE MATERIAL

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MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
RADIATION CONTROL PROGRAM
GUIDE FOR THE PREPARATION OF LICENSE APPLICATIONS FOR THE MEDICAL USE OF RADIOACTIVE MATERIAL

PART 1. INTRODUCTION

1.1 GENERAL

The Radiation Control Program of the Department of Public Health (Agency), regulates the intentional administration of radionuclides to human beings in the Commonwealth of Massachusetts. This type of use is called medical use, and a specific license is required. The regulations governing medical use are contained in 105 CMR 120.500 of the Massachusetts Regulations for Control of Radiation (MRCR), "USE OF RADIONUCLIDES IN THE HEALING ARTS".

The Agency will usually issue a single radioactive material license to cover an entire category of radioisotope programs. Separate licenses are not normally issued to different departments of a hospital or to individuals employed by a hospital. A license applicant should carefully study this guide, 105 CMR 120.500 and all the regulations identified in Section 1.2 below. The applicant should then complete the appropriate application form, Agency form MRCP 120.100-4. The Agency may request additional information to assure that the applicant has established an adequate radiation protection program.

This guide incorporates by reference NRC Regulatory Guide 10.8, Revision 2, "Guide for the preparation of Applications for Medical Use Programs", and makes references to the appendices in that guide.

1.1.1 Purpose of Guide

This guide describes the type and extent of information required by the Agency to evaluate a license application for the medical use of radioactive material.

1.1.2 Purpose of Appendices to Guide

The regulations require that the licensee develop and implement procedures that will ensure compliance with the regulations. Appendices A through R to NRC Regulatory Guide 10.8, Revision 2, and Appendix X, June 1992 describe model radiation safety procedures.

Each applicant should carefully read the applicable rules and model procedures and then decide if the model procedures are appropriate for its specific radiation safety needs.

In the application, applicants may certify that they will follow model procedure (appropriate certification language is given at the beginning of each appendix) or may say that they have developed a procedure that is enclosed for review (appropriate reference language is given at the beginning of each appendix).

References to regulations should be to 105 CMR 120.000 and not 10 CFR. TABLE 3 provides a list of relevant sections of 105 CMR 120.000 and corresponding parts of 10 CFR.

1.2 APPLICABLE RULES

In addition to 105 CMR 120.500, other regulations pertaining to the medical use of radioactive material are found in the current version of:

- 105 CMR 120.001, "General Provisions";
- 105 CMR 120.200, "Standards for Protection Against Radiation" describes radiation safety limits;
- 105 CMR 120.750, "Notices, Instructions, and Reports to Workers: Inspections" describes training information;
- 105 CMR 120.770, "Packaging and Transportation of Radioactive Material" describes limits for transporting materials; and
- 105 CMR 120.890, "Low-level radioactive waste minimization regulations general provisions".

1.3 AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

105 CMR section 120.506 states that each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable (ALARA).

The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

1.3.1 General ALARA Considerations

Each individual who is authorized to use radioactive material should provide appropriate instruction to all individuals who work with or in the vicinity of radioactive material and should ensure that the facility and equipment are adequate for safe use.

NUREG-1134, "Radiation Protection Training for Personnel Employed in Medical Facilities," provides information on training programs for use by medical use licensees. (This document is available from the U.S Nuclear Regulatory Commission.) Each worker should follow procedures developed to ensure safety and should promptly report incidents and potential problems to the authorized user or Radiation Safety Officer (RSO).

1.3.2 ALARA in Medical Institutions

Each medical licensee must have a formal ALARA program as required by 105 CMR section 120.506. The success of an ALARA program depends on the cooperation of each person who works at the licensee's facility.

Management should make a formal policy commitment to the ALARA philosophy and implement that commitment with adequate resources. A Radiation Safety Committee, composed of individuals who have special expertise in the safe use of radioactive material, is required by 105 CMR 120.508 to review uses for safety and ALARA considerations.

The Committee, the RSO, and management should audit the radioactive material program to ensure the continued safe use of radioactive material. In addition to being a member of the Committee, the RSO serves as a technical consultant to the Committee and is also responsible for the day-to-day operation of the radiation safety program.

The Nuclear Regulatory Commissions regulatory guide 8.18, ALARA Guide for Medical Institutions, contains information, methods, and references useful in establishing radiation safety programs to maintain exposures ALARA in medical institutions. The applicant should also refer to the model ALARA management program contained in Appendix G and appropriate references provided in Appendix W to the NRC regulatory guide 10.8, rev. 2.0. In general applicants should consider the ALARA philosophy in the development of plans for any work with radioactive materials.

1.4 TYPES OF LICENSES

The Agency issues three types of licenses for the use of radioactive material in the practice of medicine. They are General License, Specific License and Specific License of Broad Scope. The General License and Specific License of Broad Scope are described in detail in 105 CMR section 120.122 and 120.127 respectively. This guide is only for persons who want to apply for a specific medical use license. However, persons who are applying for other types of licenses may find the information in this guide useful in designing their radiation safety program.

1.4.1 Specific License

Specific licenses for physicians in private practice are generally limited to physicians who are located in private offices and not on hospital premises. A Radiation Safety Committee is not required. Methods of use that require hospitalization of the patient are not permitted.

Specific licenses are also issued to medical institutions. A medical institution is an organization in which several disciplines are practiced. These licenses authorize radioactive material for medical uses by physicians named on the institution's license. The rules in 105 CMR 120.508 require an institutional licensee to have a Radiation Safety Committee to oversee the use of licensed material

throughout the institution and to review the institution's radiation safety program. The physicians named on the institution's license conduct their programs with the approval of the Radiation Safety Committee.

A specific license may also be issued for a mobile nuclear medicine service (see 105 CMR 120.512). Both private practitioners and institutions may apply for authorization to use radioactive material in a mobile service.

The private use physician must confirm in writing that, if there were an emergency involving a radioactive patient, the patient could be cared for at a local hospital. Confirmation from the hospital administrator must accompany the license application.

PART 2. FILING AN APPLICATION

2.1 GENERAL FORMAT

You should apply for a license by completing Agency form MRCP 120.100-4 (Attached).

1. Complete Items 1 through 4 and 13 on the form itself. For Items 5 through 12, submit the required information on supplementary pages.

2. Identify and key each separate sheet or document submitted with the application to the item's number of the application to which it refers.

3. All typed pages, sketches, and, if possible, drawings should be on 8-1/2 x 11 inch paper to facilitate handling and review. If larger drawings are necessary, fold them to 8-1/2 x 11 inches.

4. Complete all items in the application in enough detail for the Agency to determine that your equipment, facilities, training and experience, and radiation safety program are adequate to protect health and minimize danger to life and property.

5. Please note that license applications are available for review by the public. Do not submit proprietary information unless necessary. If proprietary information is submitted without proper documentation, there may be disclosure of the proprietary information to the public or time-consuming delays in processing your application.

6. Do not submit personal information about your individual employees unless it is pertinent to the application. Training and experience of individuals should be submitted to demonstrate their ability to manage radiation safety programs or to work safely with radioactive materials. Submit home addresses and home telephone numbers only if they are part of an emergency response plan. Do not submit birthdates, Social Security numbers, and radiation dose information unless specifically requested by the Agency.

7. Retain one copy of the entire application for yourself. The license is issued based on the statements and representations in your application and any supplements to it as well as the requirements in the rules.

8. The application and all attachments should be sent to:

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
Radiation Control Program
174 Portland St., 5Th FL.
Boston, MA 02114

2.2 LICENSE FEES

An application fee is required for NEW licenses and must be submitted with the application. The applicant should refer to Massachusetts current fee schedule to determine the amount of fee that should accompany the application. Review of the application will not begin until the proper fee is received by The Radiation Control Program. The check or money order should be made payable to The Commonwealth of Massachusetts. Do not submit a fee for a license renewal or amendment. All current licensees will receive their annual invoice prior to the expiration month of their current license.

PART 3. CONTENTS OF APPLICATION

This portion of the guide explains, item by item, the information needed on Agency form MRCP 120.100-4. If you have specific questions after careful review of this guide, contact the Radiation Control Program staff at 617-727-6214.

Item 1 - LICENSE INFORMATION

For a new license, check subitem A. For an amendment to an existing license, check subitem B. For a renewal of an existing license, check subitem C.

Item 2 - APPLICANT'S NAME AND MAILING ADDRESS

If you are an individual, you should be designated as the applicant only if you are acting in a private capacity and the use of the radioactive material is not connected with your employment with a corporation or other legal entity. Otherwise, you, the applicant, should be the corporation or other legal entity applying for the license.

The address specified here should be your mailing address for correspondence. This may or may not be the same as the address at which the material will be used as specified in Item 3.

Item 3 - LOCATIONS OF USE

Specify each location of use. List the street address, city, and State or other descriptive address (such as 5 miles on Highway 10, Anytown, State) to allow us to locate your facilities. A post office box address is not acceptable.

If you will use radioactive material at more than one location, you must give the specific address of each location. You also must describe the intended use and the facilities and equipment at each location. Use Items 5 through 11 of the application to describe uses at multiple locations. If you are applying for a license for a mobile nuclear medicine service, specify so and list the name and location of each client.

Item 4 - PERSON TO BE CONTACTED ABOUT APPLICATION

Provide the name and telephone number of the individual who knows your proposed radioactive materials program and can answer questions about the application. This individual, usually the RSO or a principal user of radioactive materials, will serve as the point of contact during the review of the application and during the period of the license. If this individual is not your full-time paid employee, specify your relationship with this individual. Notify the Agency if the individual assigned to this function changes. Notification of a contact change is for information only and would not be considered an application for a license amendment.

Item 5 - RADIOACTIVE MATERIAL and Item 6 - PURPOSE

105 CMR 120.500 divides radioactive material for medical use into six types of use. Using the table format of Table 1 as a guide, you may indicate only the types of use you want and the maximum amount. You may say "As needed" in the "Amount" column as shown. For 105 CMR section 120.545 implant material, express the total amount in millicurie (mCi). If you plan to have an eye applicator, list it as a separate line item and note its total activity in mCi.

If you need other items such as

- more radioactive material for in vitro testing than is allowed under 105 CMR section 120.122(g).
- depleted uranium for linear accelerator shielding
- a survey meter calibration source
- a teletherapy dosimetry system constancy check source
- material for in vitro, animal research, or human studies or
- authorization to participate in a protocol approved by a Radioactive Drug Research Committee that has been approved by the Food and Drug Administration, make a separate line entry for each item.

Number each line entry consecutively following the 105 CMR 120.500 material. Each line entry must identify the radionuclide, the physical form, maximum amount on hand expressed in mCi, and the purpose for which the material will be used. If you do not want all the material listed in a 105 CMR 120.500, you must identify, line by line, the material that you do want from the section.

TABLE 1 - Radioactive Material, Amount & Purpose		
5. Radioactive material	Amount	6. Purpose
5a. Material in 105 CMR Section 120.532 (imaging and localization)	As needed	6a. Medical use
5b. Material in 105 CMR Section 120.636 (radiopharmaceutical for therapy)	As needed	6b. Medical use
5c. Material in 105 CMR Section 120.540 (sealed sources for diagnosis, e.g. bone analyzers)	__mCi	6c. Medical use
5d. Implant Material in (105 CMR Section 120.542)	__mCi	6d. Medical use
5e. Eye applicator in (105 CMR Section 120.542)	__mCi	6e. Medical use
5f. Material in 105 CMR Section 120.548 (sealed source in teletherapy)	__mCi	6f. Medical use

Item 7 - INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAMS--THEIR TRAINING AND EXPERIENCE

105 CMR section 120.124 requires that an applicant be qualified by training and experience to use the requested radioactive materials for the purposes requested in such a manner as to protect health and minimize danger to life or property. Responsible individuals are the authorized users, the RSO, and for teletherapy the teletherapy physicist.

105 CMR section 120.565 through 120.576 provides specific criteria for acceptable training and experience for authorized users for medical use, for the RSO, and for the teletherapy physicist. Note that curriculum vitae do not usually supply all the information needed to evaluate an individual's training and experience.

Authorized users involved in medical use have the following special responsibilities:

1. Examination of patients and medical records to determine if a radiation procedure is appropriate,

2. Prescription of the radiation dosage or dose and how it is to be administered,

3. Actual use of, or direction of technologists or other paramedical personnel in the use of, radioactive material, and

4. Interpretation of results of diagnostic procedures and evaluation of results of therapy procedures.

Numbers 1 through 4 may be delegated to a physician who is under the supervision of an authorized user. Technologists or other personnel also may use radioactive material under an authorized user's supervision as permitted in 105 CMR section 120.503. Supervision is defined in 105 CMR section 120.510.

For in vitro and animal research or other uses that do not involve the intentional exposure of humans, the list of proposed authorized users should include those individuals who will actually be responsible for the safe use of the radioactive material for the requested use. Note which user will be involved with which use by reference to Items 5 and 6 of the application. Those authorized users may direct the use of the radioactive material by technologists or other individuals for the requested use.

7.1 Authorized Users for Medical Use

1. Make a separate attachment for the RSO and each authorized user. Number the attachments "ATT 7.1.1," "ATT 7.1.2," etc. Type the full name of the individual and note, by reference to Items 5.a, 5.b, etc., which proposed uses are requested for the individual.

2. If a physician has been previously authorized for medical use and only wants to use material permitted by the previous license, you only need to submit the previous license number (if issued by the Agency) or a copy of the license (if issued by another Agreement State or NRC) on which the physician was specifically named as an authorized user.

3. If a physician is certified by an organization listed in the appropriate section of 105 CMR section 120.565 through 120.576, submit Supplement A with Items 1, 2, and 3 completed. A physician certified as a British "Fellow of the Faculty of Radiology" (FFR) or "Fellow of the Royal College of Radiology" (FRCR) should submit a copy of the certificate and evidence of specialization in radiation therapy.

4. Physicians not previously authorized by the AEC or NRC or an Agreement State **and** not certified by an appropriate organization must submit a complete description of their training and experience using Supplements A and B. This documentation will be reviewed on a case-by-case basis. If the training and experience does not appear to meet the training standards, the Agency will request the assistance of its Radiation Advisory Committee.

7.2 Authorized Users for Nonmedical Use

List the full name of each individual proposed as an authorized user for nonmedical use. Submit a complete description of the person's training and experience using Supplement A. If the individual was already identified in Item 7.1, no additional attachment is needed here.

7.3 Radiation Safety Officer

State the name and title of the person designated by, and responsible to, the applicant's management as RSO. If the RSO is not one of the proposed authorized users, submit a complete description of the individual's training and experience using Supplement A. The RSO should be a full-time employee of the licensee. Even if the licensee employs a consultant to assist the RSO, the licensee is still responsible for the radiation safety program as required by the license.

Items 8 through 11

Responses to these items may consist of one sentence that says that you will follow the model procedure in Appendix ___ in Nuclear Regulatory Commission Guide 10.8, Rev 2.0. Alternately you may choose to develop your own procedure for review. Also refer to section 1.1.2 of this guide. For the items not pertaining to your operation simply write the notation "NA" or "not applicable." Follow the instructions on the Applicability Table, Table 2, to determine whether you must provide information or may simply respond "NA" to each item that follows. Before you respond to an item, read the introductory paragraphs of the referenced appendix. Your short sentence or NA responses to Items 8 through 11 should run consecutively on one or more sheets. Lengthy responses should be appended as attachments.

If you edit a model procedure solely to identify responsible individuals, equipment by name or model, room numbers, or other site-specific information, there is no need to submit that procedure for review.

TABLE 2

APPLICABILITY TABLE

To determine those items to which you must respond, "highlight" the columns under the categories of material you requested in Item 6. If any "checkmark" beside an item is highlighted, you must provide information in response to the item. If only the letters "NA" (not applicable) are highlighted, you may respond "NA" in your application. Numbers in title column 2 through 6 refers to sections of 105 CMR.

Item	Topic	120.531	120.533	120.537	120.543	120.541	Other	App
8.1	Training program	✔	✔	✔	✔	✔	NA	A
8.2	Other training program	NA	NA	NA	NA	NA	✔	--
9.1	Annotated drawing	✔	✔	✔	✔	✔	✔	Exh. 1
9.2	Survey instrument calibration	✔	✔ B	✔	✔	✔	✔	
9.3	Dose calibrator calibration	✔	✔	✔	NA	NA	NA	C
9.4	Personnel monitor program	✔	✔	✔	✔	NA	✔	D
9.5	Imaging equipment QA for Mobile Nuc Med	(See special instructions 9.5 in the text)			E			
9.6	Other equipment & facilities	NA	NA	NA	NA	NA	✔	--
10.1	Radiation Safety Committee/Radiation Safety Officer	(See special instructions 10.1 in the text)					F	
10.2	ALARA program	(See special instructions 10.2 in the text)					G	
10.3	Leak test	✔	✔	✔	✔	✔	NA	H
10.4	Safe use of radio-pharmaceutical	✔	✔	✔	NA	NA	NA	I
10.5	Spill procedures	✔	✔	✔	NA	NA	NA	J
10.6	Ordering and receiving	✔	✔	✔	✔	✔	✔	K
10.7	Opening packages	✔	✔	✔	✔	✔	✔	L
10.8	Unit dosage records	✔	✔	✔	NA	NA	NA	M1

TABLE 2 (Continued)

Item	Topic	120.531	120.533	120.537	120.543	120.541	Other	App
10.9	Multidose vial records	✔	✔	✔	NA	NA	NA	M2
10.10	Mo-99 concentration records	NA	✔	NA	NA	NA	NA	M3
10.11	Implant source use records	NA	NA	NA	✔	NA	NA	M4
10.12	Area survey procedures	✔	✔	✔	✔	NA	✔	N
10.13	Air concentration control	NA	✔	NA	NA	NA	NA	O
10.14	Radiopharmaceutical therapy	NA	✔	NA	NA	NA	NA	P
10.15	Implant therapy	NA	NA	NA	✔	NA	NA	Q
10.16	Other safety procedures	NA	NA	NA	NA	NA	✔	--
11.1	Waste disposal	✔	✔	✔	✔	✔	NA	R
11.2	Other waste disposal	NA	NA	NA	NA	NA	✔	--
11.3	Waste minimization	✔	✔	✔	✔	✔	NA	--

Item 8 - TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

8.1 Training Program

Describe the training program for individuals who work with or near radioactive material described in 105 CMR 120.500. See Appendix A of NRC Regulatory Guide 10.8, Rev. 2.

8.2 Other Training Program

Describe the training program for individuals who handle radioactive material other than the 105 CMR 120.500 material that you listed in Item 5 of this application. Append it as ATT 8.2.

Item 9 - FACILITIES AND EQUIPMENT

9.1 Annotated Drawing

Submit an annotated drawing of the `room or rooms and adjacent areas where radioactive material will be used. Append it as ATT 9.1. Note the following:

1. The scale. Use the same scale (preferably 1/4 inch = 1 foot) for all drawings.

2. The direction of north.

3. Room numbers and principal use of each room or area (for example, in vitro, hot lab, waiting, examining, imaging, reading, office, file, fresh materials storage, radioactive waste storage, film processor, toilet, closet, hallway).

4. Any shielding available.

5. Additional safety equipment (for example, fume hoods, L-blocks, or fixed area monitors).

See NRC Regulatory Guide 10.8, Rev 2.0, Exhibit 6, for an example.

9.2 Survey Instrument Calibration

Submit your procedure for calibrating survey instruments. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix B.

9.3 Dose Calibrator Calibration

Submit your procedure for calibrating the dose calibrator. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix C.

9.4 Personnel Monitor Program

Describe your personnel occupational exposure monitor program. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix D.

9.5 Imaging Equipment

If you are transporting imaging equipment as part of a mobile nuclear medicine service, describe your procedure for checking the equipment to ensure it has not been damaged in transit. 105 CMR 120.515 requires that each licensee establish written quality control procedures for all equipment used to obtain images from radionuclide studies. Also refer to NRC Regulatory Guide 10.8, Rev 2.0, Appendix E for an example.

9.6 Other Equipment and Facilities

Describe other equipment and facilities available for the use and storage of material described in Item 5 of this application other than material described in 105 CMR 120.500. Append it as ATT 9.6.

Item 10 - RADIATION SAFETY PROGRAM

10.1 Radiation Safety Committee/Radiation Safety Officer

Describe your Radiation Safety Committee Charter and Radiation Safety Officer delegation of authority. A Radiation Safety Committee must be established by each medical institution licensee (see 105 CMR section 120.508) unless the application is only for devices listed in 105 CMR section 120.541 (such institutions will be exempted by license condition). If you are not an institution, you only need to submit the Radiation Safety Officer delegation of authority. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix F.

The Radiation Safety Committee should be appointed by the licensee's administrative management. State the procedure used to appoint the members of the RSC and to appoint the RSO.

10.2 ALARA Program

Submit your ALARA program. Each medical licensee must have an ALARA program (105 CMR section 120.506) unless the application is **only** for devices listed in 105 CMR section 120.540 (such institutions will be exempt by license condition). If you are only applying for devices in 105 CMR section 120.541, say "NA." Otherwise, see NRC Regulatory Guide 10.8, Rev 2.0, Appendix G.

10.3 Leak Test

Submit your procedure for leak testing sealed sources. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix H.

10.4 Safe Use of Radiopharmaceutical

Submit a copy of your rules for the safe use of radiopharmaceutical. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix I.

10.5 Spill Procedures

Submit a copy of your spill procedures. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix J.

10.6 Ordering and Receiving

Submit a copy of your procedure for ordering and receiving radioactive material. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix K.

10.7 Opening Packages

Submit your procedure for opening packages that contain radioactive material. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix L.

10.8 Unit Dosage Records

Submit your procedure for keeping records of unit dosage use. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix M.1.

10.9 Multidose Vial Records

Submit your procedure for keeping records of multidose vial use. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix M.2.

10.10 Molybdenum Concentration Records

Submit your procedure for measuring and recording molybdenum concentration. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix M.3.

10.11 Implant Source Use Records

Submit your procedure for keeping an inventory of implant sources. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix M.4.

10.12 Area Survey Procedures

Submit your area survey procedures. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix N.

10.13 Air Concentration Control

1. Submit your procedure for estimating worker dose from submersion in noble gases. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix O.

2. Submit your procedure for estimating worker dose from aerosol concentrations. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix O.

3. Submit your procedure for estimating aerosol and gas concentration in effluent. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix O.

4. Submit your procedure for calculating spilled gas clearance times. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix O.

10.14 Radiopharmaceutical Therapy

Submit your procedure for radiation safety during radiopharmaceutical therapy. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix P.

10.15 Implant Therapy

Submit your procedure for radiation safety during implant therapy. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix Q.

10.16 Other Safety Procedures

Submit safety procedures that will be followed by individuals who handle radioactive material described in Item 5 of this application other than material described in 105 CMR 120.500. Append them as ATT 10.16.

Item 11 - WASTE MANAGEMENT

11.1 Waste Disposal

Submit your procedures for waste disposal. See NRC Regulatory Guide 10.8, Rev 2.0, Appendix R.

11.2 Other Waste Disposal

Submit waste disposal procedures that will be followed for radioactive materials described in Item 5 of this application other than material described in 105 CMR 120.500. Append them as ATT 11.2. (If they are the same as the procedures submitted in Item 11.1, say "See Item 11.1".)

11.3 Waste Minimization

105 CMR 120.890 requires that all radioactive material users, as well as all generators, of radioactive waste must prepare a statement indicating the measures they have taken to minimize any waste that may result from their operations. Those applicants whose operation result in 100 cubic feet or more of waste per annum, and such waste requires disposal, must develop and institute waste minimization programs predicted on detailed plans. Provide an appropriate document that applies to your operation.

Item 12 - ORGANIZATIONAL STRUCTURE

Provide an organizational chart both for the institution, showing Administration, Radiation Safety Committee and Radiation Safety Officer, and for the corporate structure and ownership. Identify the state of incorporation, and provide the names of principal stockholders, if applicable. List parent companies, names, addresses, and titles of principals. List percentages of partners, shares, state of incorporation, and other organizational details that may be important during financial or legal circumstances.

Item 13 - CERTIFICATION

If the application is for a private practice, it should be signed by a senior partner of the president. If the application is for an institution, hospital, or medical center, it must be signed by its director or chief executive officer. Identify the title of the office held by the individual who signed the application.

BEFORE SUBMITTING IT, REVIEW YOUR APPLICATION TO BE SURE YOU HAVE RESPONDED TO EACH ITEM AND TO BE SURE THAT EACH PAGE THAT YOU HAVE ATTACHED HAS AN ATTACHMENT NUMBER AND IS DATED.

PART 4. AMENDMENTS TO LICENSE

A licensee must receive a license amendment before changing the scope of the program, changing the Radiation Safety Officer or teletherapy physicist, or adding to the staff of authorized users. See 105 CMR section 120.504 for the specific requirements. An application for an amendment must be filed either on agency 120.100-4 or as a letter and must be signed as described in Item 13. The teletherapy physicist's credentials must be submitted as part of the amendment application.

PART 5. RENEWAL OF A LICENSE

An application for the renewal of a license should be filed at least 60 days before the expiration date. This will ensure that the license does not expire before final action on the application has been taken by the Agency as provided for in 105 CMR section 120.133. The application for renewal must be filed on Agency form MRCP 120.100-4. The application for renewal may reference attachments that were previously submitted. For example, "See ATT 10.7 dated November 14, 1992."

TABLE 3

APPENDIX TO REG. GUIDE 10.8, Rev 2.0	REFERENCE SECTIONS	
	NRC (10 CFR)	MASSACHUSETTS (105 CMR)
A	§§ 19.12 and 35.21	§§ 120.753 and 120.565
B	§ 35.51	§ 120.518
C	§ 35.50	§ 120.517
D	§ 20.101	§ 120.211
E	§§ 35.29 and 35.80	§ 120.512 and 120.528
F	§§ 35.21, 35.22 and 35.23	§§ 120.507, 120.508 and 120.509
G	§ 35.20	§ 120.506
H	§ 35.59	§ 120.546
I	§ 35.21	§ 120.507
J	§ 35.21	§ 120.507
K	§§ 30.51 and 20.205	§§ 120.009, 130(B), 235, 246
L	§§ 35.23, 30.51, 20.203(f)(4) and 20.205	§§ 120.509, 120.009, 120.246 and 120.785(H)
M1	§§ 30.51, 35.21, 35.53	§ 120.009, 120.507 and 120.519
M3	§ 35.204	§ 120.534
N	§ 35.70	§ 120.526
O	§§ 20.103, 20.106, 20.201, 35.90 and 35.205	§§ 120.211, 120.212, 120.221, 120.529, and 120.535
P	§§ 35.300, 35.75 and 20.105	§§ 120.536, 120.526, 120.221
Q	§§ 35.75, 35.404 and 35.406	§§ 120.527, 120.547, 120.546
R	§§ 20.301, 20.303, 20.306 and 35.92	§§ 120.251, 120.253, 120.255, 120.269 120.530
T	§ 35.31	§ 120.504

RADIOACTIVE MATERIALS LICENSE APPLICATION
MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH, RADIATION CONTROL PROGRAM

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INSTRUCTIONS - Complete all items in this application for a new license or the renewal of an existing license. Use supplemental sheets where necessary. Item 13 must be completed on all applications. Mail the completed application to: The Radiation Control Program, 174 Portlans Street, 5th Fl. Boston, MA 02114. Upon approval of this application, the applicant will receive a State of Massachusetts Radioactive Material License.

1. THIS IS AN APPLICATION FOR ☐ A. NEW LICENSE ☐ B. AMENDMENT TO LIC.NO.________ ☐ C. RENEWAL OF LICENSE NO.______	2. NAME AND MAILING ADDRESS OF APPLICANT(Include zip code)
3. ADDRESSES WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.	
4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION.	TELEPHONE NUMBER
SUBMIT ITEMS 5 THROUGH 12 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.	
5. RADIOACTIVE MATERIAL a. Element & mass number; b. Chemical and/or physical form; c. Maximum amount that will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFTY PROGRAM AND THEIR TRAINING AND EXPERIENCE.	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
9. FACILITIES AND EQUIPMENT.	10. RADIATION SAFETY PROGRAM
11. WASTE MANAGEMENT (INCLUDE MINIMIZATION STATEMENT/PLAN).	12. CORPORATE STRUCTURE

ITEM 13 - CERTIFICATE (This item must be completed)

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH APPLICABLE STATE REGULATIONS AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

_______________________________________ By: _____________
TYPE OR PRINT NAME OF CERTIFYING OFFICIAL SIGNATURE

_______________________________________ Date: _______________
TITLE OF CERTIFYING INDIVIDUAL

MARCH 1994, REV. 0